ACCURATUS —LAB SERVICES— THE ANTIMICROBIAL AUTHORITY

ACCURATUS —LAB SERVICES— THE ANTIMICROBIAL AUTHORITY

AMENDMENT TO GLP TEST PROTOCOL

Amendment No.:	2
Effective Date:	October 30, 2017
Sponsor:	GOJO Industries, Inc. One GOJO Plaza, Suite #500 Akron, OH 44311
Test Facility:	Accuratus Lab Services 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121
Protocol Title:	Food Contact Sanitizer Test Method for Towelettes
Protocol Number:	GJI01083017.FCST.2
Project Number:	A24117

Modifications to Protocol:

Per Sponsor's request, the protocol is amended to update the wiping procedure. When wiping each carrier for the second time, the carriers are to be wiped left to right instead of up and down.

Changes to the protocol are accepted as noted.

Matthew Sato
Study Director

10-30-17
Date

EXACT COPY
INITIALS MS DATE 11-20-17

ACCURATUS —LAB SERVICES— THE ANTIMICROBIAL AUTHORITY

ACCURATUS —LAB SERVICES— THE ANTIMICROBIAL AUTHORITY

AMENDMENT TO GLP TEST PROTOCOL

Amendment No.:	1
Effective Date:	October 27, 2017
Sponsor:	GOJO Industries, Inc. One GOJO Plaza, Suite #500 Akron, OH 44311
Test Facility:	Accuratus Lab Services 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121
Protocol Title:	Food Contact Sanitizer Test Method for Towelettes
Protocol Number:	GJI01083017.FCST.2
Project Number:	A24117

Modifications to Protocol:

Per Sponsor's request and due to carrier population control failure, modification 1 of the protocol is amended to target an organism population of ~7.9 x 10^9 CFU/mL. At 620 nm, a 0.75 absorbance after a 1:4 dilution should target this population, however alternate absorbance values may be targeted to meet the carrier population acceptance criteria.

Changes to the protocol are accepted as noted.

Matthew Saltz — Study Director

10-27-17 — Date

EXACT COPY
INITIALS MS DATE 11-20-17

(For Laboratory Use Only)
Accuratus Lab Services Project # A24117 8-29-17
Test Substance Tracking # T5092017.GJI01
T5092017.GJI01
pmt 9-20-17
T5092617.GJI01 MS9-29-17

ACCURATUS LAB SERVICES

PROTOCOL

Food Contact Sanitizer Test Method for Towelettes

Test Organism(s):

Staphylococcus aureus (ATCC 6538)

PROTOCOL NUMBER

GJI01083017.FCST.2

PREPARED FOR/SPONSOR

GOJO Industries, Inc.
One GOJO Plaza, Suite #500
Akron, OH 44311

PREPARED BY/TESTING FACILITY

Accuratus Lab Services
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

DATE

August 30, 2017

EXACT COPY
INITIALS MS DATE 11-20-17

Food Contact Sanitizer Test Method for Towelettes

PURPOSE
The purpose of this assay is to determine the sanitizing efficacy of towelettes recommended for the treatment of hard, non-porous surfaces which may come into contact with food. This method is in compliance with the requirements of and may be submitted to, one or more of the following agencies as indicated by the Sponsor: U.S. Environmental Protection Agency (EPA) and Health Canada.

TEST SUBSTANCE CHARACTERIZATION
According to 40 CFR, Part 160, Subpart F [160.105] test substance characterization as to identity, strength, purity, solubility and composition, as applicable, shall be documented before its use in this study. The stability of the test substance shall be determined prior to or concurrently with this study. Pertinent information, which may affect the outcome of this study, shall be communicated in writing to the Study Director upon sample submission to Accuratus Lab Services. Accuratus Lab Services will append Sponsor-provided Certificates of Analysis (C of A) to this study report, if requested and supplied. Characterization and stability studies not performed following GLP regulations will be noted in the Good Laboratory Practice compliance statement.

SCHEDULING AND DISCLAIMER OF WARRANTY
Experimental start dates are generally scheduled on a first-come/first-serve basis once Accuratus Lab Services receives the Sponsor approved/completed protocol, signed fee schedule and corresponding test substance(s). Based on all required materials being received at this time, the proposed experimental start date is September 13, 2017. Verbal results may be given upon completion of the study with a written report to follow on the proposed completion date of October 11, 2017. To expedite scheduling, please be sure all required paperwork and test substance documentation is complete/accurate upon arrival at Accuratus Lab Services.

If a test must be repeated, or a portion of it, due to failure by Accuratus Lab Services to adhere to specified procedures, it will be repeated free of charge. If a test must be repeated, or a portion of it, due to failure of internal controls, it will be repeated free of charge. "Methods Development" fees shall be assessed, however, if the test substance and/or test system require modifications due to complexity and difficulty of testing.

If the Sponsor requests a repeat test, they will be charged for an additional test. Neither the name of Accuratus Lab Services nor any of its employees are to be used in advertising or other promotion without written consent from Accuratus Lab Services

The Sponsor is responsible for any rejection of the final report by the regulatory agencies concerning report format, pagination, etc. To prevent rejection, Sponsor should carefully review the Accuratus Lab Services final report and notify Accuratus Lab Services of any perceived deficiencies in these areas before submission of the report to the regulatory agency. Accuratus Lab Services will make reasonable changes deemed necessary by the Sponsor, without altering the technical data.

JUSTIFICATION FOR SELECTION OF THE TEST SYSTEM
Regulatory agencies require that a specific organism claim for a sanitizer intended for use on food contact surfaces be supported by appropriate scientific data demonstrating the efficacy of the sanitizer against the claimed bacteria. This is accomplished by treating the target bacteria with the sanitizer (test substance) under conditions which simulate as closely as possible, in the laboratory, the actual conditions under which the sanitizer is designed to be used. For saturated towelette sanitizer products intended for use on food contact surfaces, a carrier method is used in the generation of the supporting data. Regulatory agencies recommend that three lots of product be tested against *Staphylococcus aureus* and *Escherichia coli,* minimally, on smooth stainless steel or glass and rough textured plastic surfaces treating at least 4 square feet per towelette. Sanitizing efficacy should be demonstrated within 30 seconds of exposure. The experimental design in this protocol meets these requirements. Health Canada requires the product be a broad spectrum or hospital grade disinfectant before sanitizer claims may be made.

TEST PRINCIPLE

Test carriers will be inoculated with a test organism suspension and will be dried. Following drying, the carriers will be treated with the pre-saturated towelette and exposed to the test substance for the Sponsor specified exposure time. After exposure, each carrier is neutralized and assayed for survivors. Appropriate initial suspension (time zero analysis), culture purity, sterility, carrier population and neutralization confirmation controls will be performed. The current revision of Standard Operating Procedure CGT-0025 reflects the method used in this study.

TEST METHOD

Table 1:

Test Organism	Designation #	Growth Medium	Incubation Parameters
Staphylococcus aureus	6538	Nutrient Agar A & B	35-37°C, aerobic

The test organism(s) to be used in this study was/were obtained from the American Type Culture Collection (ATCC), Manassas, VA.

Preparation of Test Organism

In a manner consistent with the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants method, streak a loopful of a thawed cryovial of stock organism broth culture to a Nutrient agar A slant medium. Incubate at 35-37°C for 24±2 hours.

For the final test culture, add up to 5 mL of Phosphate Buffer Dilution Water (PBDW) to the Nutrient Agar A slant, following incubation. Using a sterile loop, dislodge growth from the agar surface. Collect the mixture and transfer to a vessel containing 99 mL of PBDW and mix thoroughly. Inoculate Nutrient Agar B plates (a minimum of 10 is recommended for the test) using 200 µL of culture, spreading the inoculum to create a lawn of growth. Incubate the plates at 35-37°C for 24±2 hours.

Following incubation, add up to 5 mL of Phosphate Buffered Saline + 0.1% Tween 80 to each plate. Using a sterile rod/plate spreader, gently dislodge the culture from the agar surface. Avoid disrupting the agar. Collect and combine the culture, then mix thoroughly. Filter the collected culture through sterile Whatman #2 filter paperwork① using a vacuum source. Standardize the culture **(see modification #1 for target concentration)**. Applicable culture dilutions will be prepared using PBDW. An organic soil load will be added to the test culture per Sponsor's request. The final test culture will be mixed thoroughly prior to use.

Carriers

Sponsor provided carriers (textured plastic or ~~glass~~ WC Stainless Steel MS 9-28-17) will be used for testing. Each carrier is approximately 12" x 12" in size. Four carriers will be tested per test substance/organism to represent approximately 4 square feet. Carriers will be sterilized prior to use.

Contamination of Carriers

Each test and control carrier will be individually inoculated with culture in a drop-wise fashion, 5 µL aliquots in 5 rows, for a total of 125 µL. The inoculum will then be spread over the inoculated surface using a sterile plate spreader or loop. The inoculation procedure will be repeated until all carriers in the set have been inoculated. The carriers will be loosely covered and allowed to dry for 30±1 minutes at **30±5°C**. The actual drying conditions will be clearly documented.

Preparation of Test Substance

Towelettes (wipes) saturated with test substance will be supplied by Sponsor. Prior to testing, 3 wipes will be dispensed and discarded.② If a wipe canister has not been used within 2 hours, 3 additional wipes will be discarded.

Exposure Conditions

One towelette will be used to treat a set of four inoculated and dried carriers using a new area of the folded wipe per carrier. The entire surface (~12" x ~12") of each carrier will be wiped. Triplicate sets carriers will be treated per test lot, using a new wipe for each set of 4 carriers. Following wiping, each carrier will be allowed to expose for the exposure time at room temperature.

①WC MS 9-28-17
②Additional wipes may be discarded as needed MS 9-28-17

Test System Recovery
For the treated carriers- Following the exposure period, each carrier will be placed in separate sterile bags with 500 mL of appropriate neutralizer. Gently mix each bag by hand to ensure full elution of the organism films for approximately 2 minutes.① ~~Following neutralization, ten-fold serial dilutions will be prepared.~~ Duplicate 1.0 mL aliquots of the 10^0 dilution will be plated. In addition, neutralizer **(2 volumes, see modification 2)** will be transferred to sterile 0.2-0.45 µm filter apparatus systems pre-wetted with 10 mL sterile diluent and will be filtered. Each filter will be rinsed using ≥50 mL of sterile diluent. The filters will be removed and placed onto the surface of agar plates appropriate for recovery of the organism.

Incubation and Observation
The subculture plates and controls will be incubated for 48±2 hours under the conditions listed on table 1. Following incubation, the subcultures will be visually examined for growth. If necessary, the subcultures may be placed at 2-8°C for up to three days prior to examination.

Representative subculture plates showing growth will be stained and/or biochemically assayed to confirm or rule out the presence of the test organism. Additional subcultures may be performed if necessary.

STUDY CONTROLS

Initial Suspension Control (Time Zero Analysis)
In order to evaluate the titer of culture delivered onto each test and control carrier as a time zero analysis, each prepared test organism suspension will be serially diluted using a sterile diluent. A 0.1 mL aliquot of appropriate dilutions will be plated, in duplicate. The plates will be incubated as in the test. Following incubation, the plates will be visually observed and enumerated to determine CFU per mL delivered onto each carrier. This control is performed and reported for informational purposes only.

Purity Control
A "streak plate for isolation" will be performed on each test organism suspension. Following incubation, the plates will be examined in order to confirm the presence of a pure culture. The acceptance criterion for this study control is a pure culture demonstrating colony morphology typical of the test organism.

Organic Soil Load Sterility Control
Prior to or concurrent with testing and if applicable, the serum used for the soil load will be added to a tube of Fluid Thioglycollate medium, incubated, and visually examined for lack of growth. The acceptance criterion for this study control is lack of growth.

Neutralizer Sterility Control
Prior to or concurrent with testing, a representative sample of uninoculated neutralizer (1.0 mL) will be spread plated on appropriate agar. The plate will be incubated and visually examined. The acceptance criterion for this study control is lack of growth.

Carrier Population Control
Four carriers per carrier type/organism will be inoculated and dried as in the test. Following drying, the first carrier in the set will be neutralized in 500 mL of neutralizer and mixed as in the test. Following mixing, aseptically remove the first carrier and discard, then transfer the second carrier to the bag and mix again. Repeat the same procedure for the 3rd and 4th carrier. The neutralized subcultures will be serially diluted and spread-plated using duplicate 0.1 mL aliquots of dilutions ~~10^{-3} through 10^{-7}~~ 10^{-2} through 10^{-4}.②

This control is used for calculating reductions observed in the test. The acceptance criterion for this study control is **(see modification 3)**.

①Removed for clarity, no serial dilutions needed. MS9-28-17
②Updated per 9-15-17 email MS9-28-17

Neutralization Confirmation Control
This control may be performed prior to or concurrent with testing. An uninoculated carrier will be wiped as in the test and neutralized in 500 mL of neutralizer. The neutralized material will be mixed and 50 mL will be distributed between each test organism dilution evaluated. Each distributed aliquot of neutralized material will be inoculated with a low level of test organism to target approximately 100 CFU of neutralized material and mixed. The entire contents will then be transferred to individual sterile 0.2-0.45 µm filter apparatus system pre-wetted with 10 mL sterile diluent. The sample will be filtered, rinsed and plated as in the test.

A numbers control will be performed by filter plating an identical aliquot of the test organism. All resulting plates will be incubated as in the test and enumerated. The acceptance criterion for this study control is growth within 1 $\log_{10}$ of the corresponding numbers control.

PROCEDURE FOR IDENTIFICATION OF THE TEST SYSTEM

Accuratus Lab Services maintains Standard Operating Procedures (SOPs) relative to efficacy testing studies. Efficacy testing is performed in strict adherence to these SOPs which have been constructed to cover all aspects of the work including, but not limited to, receipt, log-in, and tracking of biological reagents including test organism strains for purposes of identification, receipt and use of chemical reagents. These procedures are designed to document each step of efficacy testing studies. Appropriate references to medium, batch number, etc. are documented in the raw data collected during the course of each study.

Additionally, each efficacy test is assigned a unique Project Number when the protocol for the study is initiated by the Study Director. This number is used for identification of the test subcultures, etc. during the course of the test. Test subcultures are also labeled with reference to the test organism, experimental start date, and test product. Microscopic and/or macroscopic evaluations of positive subcultures are performed in order to confirm the identity of the test organism. These measures are designed to document the identity of the test system.

METHOD FOR CONTROL OF BIAS: NA

STUDY ACCEPTANCE CRITERIA

Test Substance Performance Criteria
The efficacy performance requirements for non-residual sanitization of hard, inanimate, food contact surfaces using pre-saturated towelettes state that a sanitizer must show at least a 99.999% (5 $\log_{10}$) reduction of the test organism over the total treated area within 30 seconds on each carrier type.

Control Acceptance Criteria
The study controls must perform according to the criteria detailed in the study controls description section. If any of the control acceptance criteria are not met, the test may be repeated under the current protocol. If the population control fails to meet the minimum requirement and growth is observed on the test plates, no repeat testing is necessary.

If any portion of the protocol is executed incorrectly warranting repeat testing, the test may be repeated under the current protocol number. If the population control fails to meet the minimum requirement or if the neutralization control acceptance criteria is not met and the study fails to meet the efficacy requirements, repeat testing is not required.

REPORT

The report will include, but not be limited to, identification of the sample, date received, initiation and completion dates, identification of the organism strains used, description of media and reagents, description of the methods employed, tabulated results and conclusion as it relates to the purpose of the test, and all other items required by 40 CFR Part 160.185.

PROTOCOL CHANGES

If it becomes necessary to make changes in the approved protocol, the revision and reasons for changes will be documented, reported to the Sponsor and will become a part of the permanent file for that study. Similarly, the Sponsor will be notified as soon as possible whenever an event occurs that may have an effect on the validity of the study.

Standard operating procedures used in this study will be the correct effective revision at the time of the work. Any minor changes to SOPs (for this study) or methods used will be documented in the raw data and approved by the Study Director.

TEST SUBSTANCE RETENTION

It is the responsibility of the Sponsor to retain a sample of the test substance. All unused test substance will be discarded following study completion unless otherwise indicated by Sponsor.

RECORD RETENTION

Study Specific Documents

All of the original raw data developed exclusively for this study shall be archived at Accuratus Lab Services for a minimum of five years for GLP studies or a minimum of six months for all other studies following the study completion date. After this time, the Sponsor (or the Sponsor Representative, if applicable) will be contacted to determine the final disposition. These original data include, but are not limited to, the following:

1. All handwritten raw data for control and test substances including, but not limited to, notebooks data, forms and calculations.
2. Any protocol amendments/deviation notifications.
3. All measured data used in formulating the final report.
4. Memoranda, specifications, and other study specific correspondence relating to interpretation, and evaluation of data, other than those documents contained in the final study report.
5. Original signed protocol.
6. Certified copy of final study report.
7. Study-specific SOP deviations made during the study.

Facility Specific Documents

The following records shall also be archived at Accuratus Lab Services. These documents include, but are not limited to, the following:

1. SOPs which pertain to the study conducted.
2. Non study-specific SOP deviations made during the course of this study which may affect the results obtained during this study.
3. Methods which were used or referenced in the study conducted.
4. QA reports for each QA inspection with comments.
5. Facility Records: Temperature Logs (ambient, incubator, etc.), Instrument Logs, Calibration and Maintenance Records).
6. Current curriculum vitae, training records, and job descriptions for all personnel involved in the study.

REFERENCES

1. Association of Official Analytical Chemists (AOAC) Official Method 960.09, Germicidal and Detergent Sanitizing Action of Disinfectants Method. In Official Methods of Analysis of the AOAC, 2013 Edition.
2. U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2000: General Considerations for Uses of Antimicrobial Agents, September 4, 2012.
3. U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2300: Sanitizers for Use on Hard Surfaces- Efficacy Data Recommendations, September 4, 2012.
4. U.S. Environmental Protection Agency, Draft Interim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes, April 12, 2001.
5. Health Canada, January, 2014. Guidance Document – Safety and Efficacy Requirements for Hard Surface Disinfectant Drugs.
6. Health Canada, January, 2014. Guidance Document - Disinfectant Drugs.

DATA ANALYSIS

Calculations:
Percent and $\log_{10}$ reductions will be determined for the treated surfaces based on the population control.

Initial Suspension Control

$$\text{CFU/mL} = \frac{\text{(average number colonies/plate @ dilution) x (dilution factor)}}{\text{(volume plated in mL)}}$$

Test Results and Carrier Population Control (CFU/carrier):

$$\text{CFU/carrier} = \frac{\text{(average number colonies/plate @ dilution) x (dilution factor) x (volume of neutralizer in mL)}}{\text{(volume plated or filtered in mL)}}$$

Total Test Survivors = $\text{CFU/Carrier}_1 + \text{CFU/Carrier}_2 + \text{CFU/Carrier}_3 + \text{CFU/Carrier}_4$
Total Carrier Population= CFU/Carrier (4 combined)
When adding CFU/carrier results together, round the final value using the CFU/carrier result with the most digits.

Log_{10} and Percent Reductions

Log_{10} reduction = Log_{10} (Total Carrier Population) – Log_{10} (Total Test Survivors)

Percent reduction = $[(a - b) / a] \times 100$

where:
a = Total Carrier Population
b = Total Test Survivors

Statistical Analysis:
None used.

STUDY INFORMATION

(All blank sections are completed by the Sponsor or Sponsor Representative as linked to their signature, unless otherwise noted.)

Test Substance (Name & Batch Numbers exactly as it should appear on final report):
2017-JigSAW-008; Batches 2017-JigSAW-008-1, 2017-JigSAW-008-2, 2017-JigSAW-008-3
Testing at the lower certified limit (LCL) is required for registration, no aged batch is necessary.

Product Description:
☐ Quaternary ammonia ☐ Peracetic acid ☐ Iodophor ☐ Peroxide
☐ Sodium hypochlorite ☒ Other Ethanol

Approximate Test Substance Active Concentration (upon submission to Accuratus Lab Services):
~19% Ethanol
(This value is used for neutralization planning only. This value is not intended to represent characterization values.)

Neutralization/Subculture Broth: ☐ _____
☑ Accuratus Lab Services' Discretion. By checking, the Sponsor authorizes Accuratus Lab Services, at their discretion, to perform neutralization confirmation assays at the Sponsor's expense prior to testing to determine the most appropriate neutralizer. (See Fee Schedule).

Storage Conditions:
☑ Room Temperature
☐ 2-8°C
☐ Other: _____

Hazards:
☑ None known: Use Standard Precautions
☒ Material Safety Data Sheet, Attached for each product
☐ As Follows: _____

Product Preparation
☑ No dilution required, Use as received (RTU)

Test Organism(s): ☑ *Staphylococcus aureus* (ATCC 6538)

Number of carriers: Triplicate sets of 4 per batch

Exposure Time: 23 seconds

Surface Type: ☐ Glass ☐ Rough (textured) plastic ☑ Stainless steel

Total Surface Area: ☑ 4 carriers to represent approximately 4 square feet

Exposure Temperature: Room temperature (18-25°C)

Organic Soil Load:
☑ **6%** Organic Soil Load (Fetal Bovine Serum in Organism Suspension)

Wiping Procedure: Wipes will be folded in half twice before use (sized to make close to an even square)

☑ Carrier 1 of 4: starting from bottom left corner, wipe upward and back to start, then move over to the right one towelette length and perform again. This will be done four total times to cover the entire carrier, taking ~15 seconds. Then flip the towelette to use the other side and perform the same wiping a second time, taking ~15 seconds (total wiping time per carrier is ~30 seconds before the exposure time starts).
Then for carrier 2: open one fold of the wipe and fold the other direction, exposing two unused sides, and wipe as stated above. Next open the wipe completely, inverting and folding as in the beginning to expose unused sides for wiping of carriers 3 and 4 as stated for the first two carriers.

TEST SUBSTANCE SHIPMENT STATUS

(This section is for informational purposes only.)

☑ Test Substance is already present at Accuratus Lab Services.
☐ Test Substance has been or will be shipped to Accuratus Lab Services.
Date of expected receipt at Accuratus Lab Services: _____
☐ Test Substance to be hand-delivered (must arrive by noon at least one day prior to testing or other arrangements made with the Study director).

COMPLIANCE

Study to be performed under EPA Good Laboratory Practice regulations (40 CFR Part 160) and in accordance to standard operating procedures.
☑ Yes
☐ No (Non-GLP or Development Study)

REGULATORY AGENCY(S) THAT MAY REVIEW DATA

☑ U.S. EPA
☐ Health Canada

PROTOCOL MODIFICATIONS

☐ Approved without modification
☑ Approved with modification

Modification 1: Target 7.0x10^8 CFU/mL with ~~0.100~~ ~0.48 Ø absorbance at 620 nm

Modification 2: Filter 50 mL and 100 mL

Modification 3: Total recovery off 4 control carriers at least 7.5 x 10^7 CFU

Modification 4: calculations performed by averaging the 3 replicates, inversing for geometric mean and then calculating for percent and log reduction. Added per 9-15-17 email. MS 9-28-17

PROTOCOL ATTACHMENTS

Supplemental Information Form Attached - ☐ Yes ☑ No
① Updated per 9-29-17 email MS 9-29-17

TEST SUBSTANCE CHARACTERIZATION & STABILITY TESTING
[Verification required per 40 CFR Part 160 Subpart B (160.31(d))].

☐ Characterization/Stability testing is not required (For Non-GLP or Development testing only)

OR

Physical and Chemical Characterization (Identity, purity, strength, solubility, as applicable) of the test lots

☒ **Physical & Chemical Characterization has been or will be completed prior to efficacy testing.**

GLP compliance status of physical & chemical characterization testing:
☒ Testing was or will be performed following 40 CFR Part 160 GLP regulations
☐ Characterization has not been or will not be performed following GLP regulations

Check and complete the following that apply:
☒ A Certificate of Analysis (C of A) may be provided for each lot of test substance. If provided, the C of A will be appended to the report.
☐ Testing has been or will be conducted at Accuratus Lab Services under protocol or study #: _____
☐ Test has been or will be conducted by another facility under protocol or study #: _____

☐ **Physical & Chemical Characterization was not or will not be performed prior to efficacy testing.**

Stability Testing of the formulation

☒ **Stability testing has been or will be completed prior to or concurrent with efficacy testing.**

GLP compliance status of stability testing:
(GLP compliance is required by 40 CFR Part 160)
☒ Testing was or will be performed following 40 CFR Part 160 GLP regulations
☐ Stability testing has not been or will not be performed following GLP regulations

Check and complete the following that apply:
☐ Testing has been or will be conducted at Accuratus Lab Services under protocol or study #: _____
☐ Test has been or will be conducted by another facility under protocol or study #: _____

☐ **Stability testing was not or will not be performed prior to or concurrent with efficacy testing.**

If test substance characterization or stability testing information is not provided or is not performed following GLP regulations, this will be indicated in the GLP compliance statement of the final report

APPROVAL SIGNATURES

SPONSOR:

NAME: Ms. Rachel Leslie TITLE: ~~Sr. Scientist - Clinical~~ Clinical Manager 9/12/17

SIGNATURE: [signature] DATE: 9/12/17

PHONE: (440) 488 - 2259 FAX: _____ EMAIL: leslier@GOJO.com

For confidentiality purposes, study information will be released only to the sponsor/representative signing the protocol (above) unless other individuals are specifically authorized in writing to receive study information.

Other individuals authorized to receive information regarding this study: ☐ See Attached

Accuratus Lab Services:

NAME: Matthew Sathe
Study Director

SIGNATURE: [signature] DATE: 9-29-17
Study Director